

Force of Cochlear Implant Electrode Insertion Performed by a Robotic Insertion Tool: Comparison of Traditional Versus Advance Off-Stylet Techniques

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Objective: Robotic cochlear implant electrode array insertion offers substantial potential advantages, namely repeatability and minimization of insertion forces, leading to decreased intracochlear trauma. Using such a robotic insertion tool, we sought to analyze force profiles during deployment of stylet-containing electrode arrays using either traditional insertion, in which the stylet is withdrawn after complete insertion of the electrode, or Advance Off-Stylet (AOS) insertion, in which the stylet is withdrawn simultaneous with electrode array insertion.

Study Design: Prospective.

Setting: Tertiary referral center.

Interventions: A robotic cochlear implant insertion tool coupled with a force-sensing carriage was used to perform electrode array insertions into an anatomically correct, three-dimensional scala tympani model during either straight insertion (n = 4) or AOS insertion (n = 4).

Main Outcome Measures: Both insertion techniques begin with a 7-mm straight insertion during which forces were similar averaging approximately 0.006 N. For insertion from 7 to 17 mm, traditional insertion forces averaged 0.046 ± 0.027 N, with a peak of 0.093 N, and AOS insertion forces averaged 0.008 ± 0.006 N, with a peak of 0.034 N. Beyond 9.74 mm, the difference between traditional and AOS insertion forces was highly significant.

Conclusion: With the use of a robotic insertion tool, which minimizes operator variability and maximizes repeatability, we have shown that cochlear implant electrode insertion via AOS is associated with lower average and maximum insertion forces compared with traditional insertion. These findings support the use of AOS over traditional, straight insertion. **Key Words:** Advance Off-Stylet insertion—Force measurement—Robotic insertion—Traditional insertion.

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Recent cochlear implant electrode designs have been aimed at decreasing intracochlear trauma, which is thought to lead to better preservation of residual hearing and improved postoperative audiological performance. One such electrode, the Freedom Advance electrode (Cochlear Corporation, Sydney, Australia), uses a stylet to keep the electrode straight during entry. When the stylet is withdrawn, the electrode assumes a precoiled shape to better conform to the quasihelical geometry of the cochlea. When first introduced, the recommended technique was to completely insert the electrode after

which the stylet would be withdrawn. This technique was then refined to the Advance Off-Stylet (AOS) technique in which, after insertion to a specified distance, the electrode is advanced while the stylet is held in place relative to the cochlea. The AOS technique is designed to limit physical contact between the electrode array and the lateral wall of the cochlea, with the intent of decreasing the likelihood of intracochlear damage (1). We sought to determine differences between AOS and traditional insertion by quantifying the force of insertion.

One of the difficulties in quantifying differences between insertion techniques is that human operators demonstrate a high degree of variability between trials. To maximize repeatability and minimize intertrial variability, an automated insertion technique is necessary. Previous reports have demonstrated that automated cochlear implant electrode insertion with robotic devices is feasible (2–8). Using such devices, the authors of these reports

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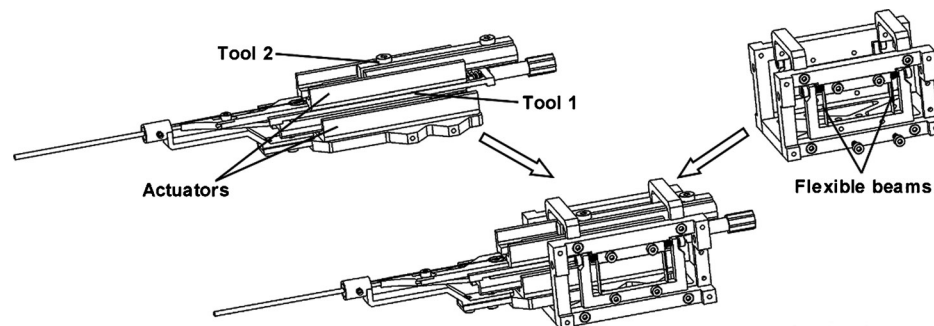


FIG. 1. The insertion robot is composed of an insertion mechanism like described in Hussong et al. (3,4) (top left) and a force-sensing unit (top right).

have analyzed the cochlear structure and behavior of different types of electrode arrays trying to find optimal insertion trajectories and velocities in patient stress during and electrode position after insertion.

Zhang et al. (2) used an insertion robot with integrated force sensing, offering 4 degrees of freedom, for their studies on insertion trajectories and velocity. However, their large, stationary device has been developed for experimental purposes and will require significant changes in design before it can be used in the operating room. Hussong et al. (3,4) and Rau et al. (5) used a much smaller, portable robot with only 1 degree of freedom that could be introduced into the operating room. However, their initial design did not include integrate force sensing and required a stationary, external device to measure force during insertion. We modified the design of Hussong et al. to incorporate a forces sensing carriage that is integrated into the tool, thus allowing intraoperative measurement independent of weight of insertion target (e.g., isolated temporal bone or whole head preparation) (7,8). Using this modified tool, we sought to quantify the differences in 2 common cochlear implant insertion techniques—AOS and traditional insertion—performing these insertions with micrometer precision and eliminating the confounding effects of human variability in experimental results.

MATERIALS AND METHODS

The insertion tool of the original design of Hussong et al. (3,4) and Rau et al. (5), with modifications by Schurzig et al. (7,8), was used in the current study (Fig. 1). Central to the original design is the use of 2 linear actuators (Model SL2060; SmarAct GmbH, Oldenburg, Germany) in which tools used to grasp specific portions of the electrode are attached. The first actuator and tool assembly is used to grasp the electrode array via a modified surgical alligator forceps (Model 180800FX; Fentex Medical, Inc., Neuenhausen ob Eck, Germany). The second actuator and tool assembly is used to hold the stylet via a stainless steel hooked wire. While inserting, a tube with an outer diameter of 1.83 mm at the front of the insertion mechanism guides the electrode array to the target and also supports the 2 tool assemblies (Fig. 1, top left).

Coupled to the insertion tool is a force-sensing carriage (Fig. 1, top right). The carriage uses 4 flexible aluminum beams to

transform the force along the axis of insertion into deformation, which can be measured by 4 semiconductor strain gauges (Model SS-060-033-1000PB; Micron Instruments, Inc., Simi Valley, CA, USA). As such, the electrical readout of the strain gauges can be calibrated to reflect force of insertion. Furthermore, the carriage was designed such that the deformation and subsequent electrical readout from the strain gauges can be zeroed out before insertion experiments. A force resolution of 0.001 N is achievable with this setup.

An anatomically correct, three-dimensional model of the scala tympani component of the cochlea (Med-el Corp., Innsbruck, Austria) was used for experimentation. It was filled with soapy water to mimic intracochlear conditions. The insertion tool was loaded with a Freedom Advance cochlear implant electrode, and the tool was positioned vertically above the model. This experimental setup is shown in Figure 2. Five insertions were performed each for straight insertion and AOS insertion. During these insertions, the force in the insertion direction resulting

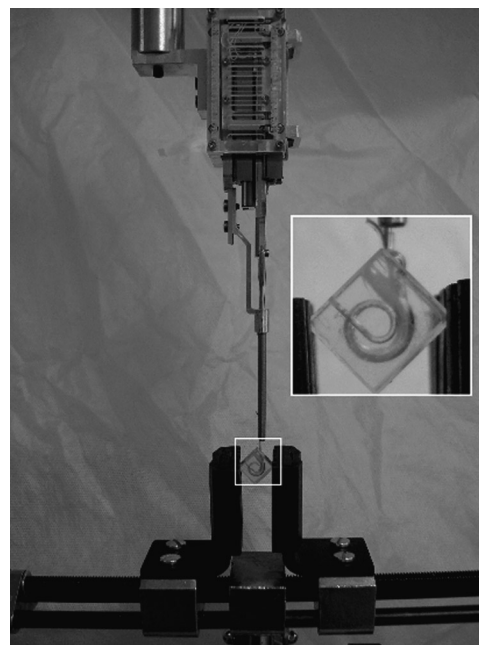


FIG. 2. The insertion robot positioned above the scala tympani model for electrode insertion experiments.

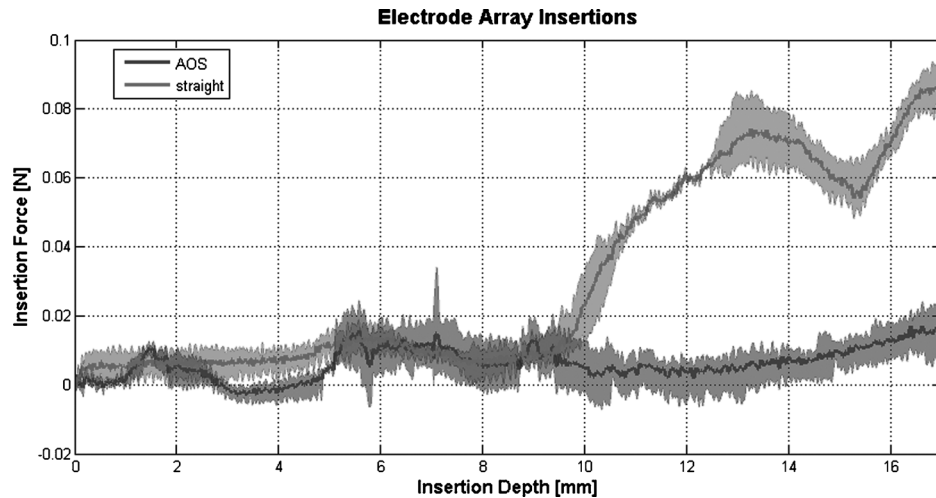


FIG. 3. Insertion forces recorded with the force-sensing insertion tool. The *solid lines* represent the average force of AOS and straight insertion technique, and the *shaded regions* show the variability in insertion forces.

from the contact between electrode array and the scala tympani model was recorded with reference to the insertion depth in mm. The resulting force profiles were analyzed, calculating average and peak insertion forces, and were compared using confidence intervals.

RESULTS

In all 8 cases, the electrode array was successfully inserted 17 mm deep into the scala tympani. Measured insertion forces are presented in Figure 3 where individual experiments as well as averaged data are shown. Average force recorded during the first 7 mm was 0.004 ± 0.006 N for AOS and 0.008 ± 0.004 N for the straight insertion. Inside the spiral of the cochlea, during AOS deployment, average forces were 0.008 ± 0.006 N for AOS and 0.046 ± 0.027 N for the straight insertion. Force

maxima were 0.034 N for AOS and 0.093 N for the straight insertion.

Because the first 7 mm of both insertion techniques are the same, we calculated the 99.9% confidence interval (bias-corrected, bootstrapped) for the absolute value difference between the 2 techniques. In Figure 4, we present these data noting that the difference between the insertion techniques exceeds the 99.9% confidence interval at an insertion depth of 9.74 mm.

DISCUSSION

Using a highly reliable robotic insertion tool, we have shown that AOS insertion is associated with significantly lower insertion force than traditional insertion in which the electrode is maximally advanced and the stylet is

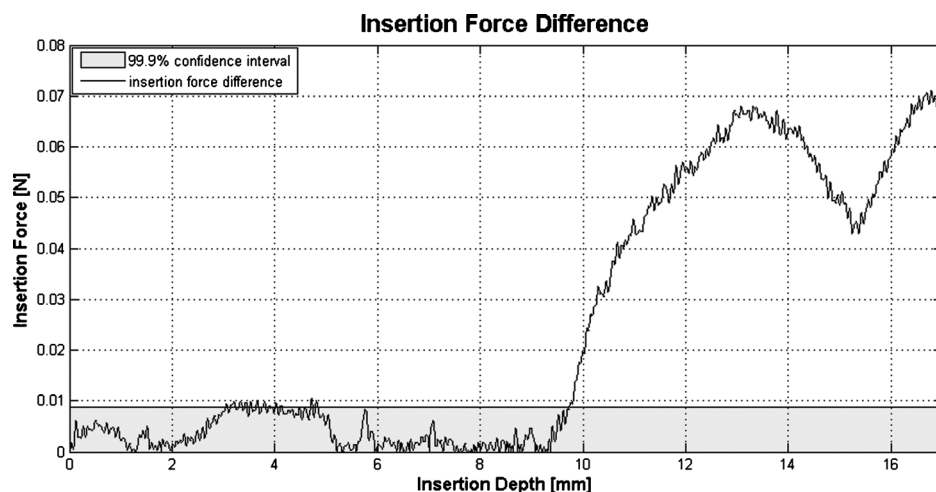


FIG. 4. Absolute difference of force between AOS and traditional insertion. The *straight line* at 0.0087 N shows the 99.9% confidence interval of the first 7-mm depth of insertion. Note that the force difference exceeds this interval at an insertion depth of 9.74 mm.

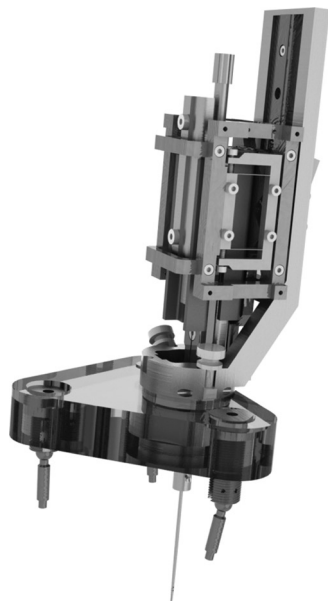


FIG. 5. CAD drawing of the insertion robot mounted onto the microstereotactic frame for optimal positioning relative to the target.

withdrawn. It is a logical extension of this that less intracochlear trauma would occur especially considering that the rupture force of the basilar member in a human cadaver is 0.029 to 0.039 N (9) and that AOS forces routinely remained below this limit (0.008 ± 0.006 N), whereas traditional insertion forces exceeded it (0.046 ± 0.027 N). Thus, AOS may allow better scala tympani placement, which has been associated with better audiological outcomes (10–12).

Our robotic insertion results are similar to a previous work that compared different cochlear electrode insertion techniques (performed manually), as documented by Todd et al. (13). Our data show a statistically significant difference between the 2 techniques at an insertion depth of 9.74 mm. Although not statistically analyzed, Todd et al. noticed a qualitative divergence at approximately 8.5 mm.

Also central to minimizing insertion forces, because of the friction between the cochlea and the electrode array, is the correct alignment of the electrode tangent to the basal turn of the cochlea (14,15). Although this is easy to do in vitro with a transparent model, in vivo alignment of the electrode in the proper orientation is vital for avoiding contact with intracochlear anatomy because such contact results in increased insertion forces and soft tissue trauma. One potential solution that our group is working on is using image-guided surgical techniques to ensure optimal alignment of the electrode with the axis of the basal turn

of the cochlea. We have reported on the use of microstereotactic frames to precisely target the scala tympani based on a patient's individual anatomy (16,17). We are currently investigating the use of such microstereotactic frames to guide the robotic insertion tool in temporal bone specimens as shown in Figure 5.

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